REMARKS

As filed, the Application included claims 1-14, no claims were added by preliminary amendment, and no claims stand withdrawn from consideration. The Amendment and Response filed on September 18, 2002, amended Claim 14 and added new claims 15 and 16. Hence, the Application now includes claims 1-16 for examination. In view of the following arguments and citations, allowance of all claims is respectfully requested.

Drawings

The Examiner approved the proposed drawing changes filed on September 18, 2002. A complete set of formal drawings is being filed in conjunction with filing of this paper, including Figure 4 with the approved drawing changes.

Claim Rejection - 35 USC § 103 Gonzalez

Claims 15 and 16 stand rejected in paragraph 6 under 35 USC § 103(a) as being obvious and unpatentable over U.S. Patent No. 6,328,689, issued December 11, 2001, to Gonzalez in view of Fawzi et al. The Gonzalez patent reflects on its face that Spiration, Inc., of Redmond, Washington, is the Assignee. The instant application is also assigned to Spiration Inc. by the inventors in an assignment recorded July 10, 2001, the same day the instant application was filed. A copy of the recorded assignment is attached hereto.

At the time the instant invention was made, the invention was owned by Spiration Inc., and the inventors were subject to an obligation of assignment to Spiration Inc. as reflected in the recorded assignment. The Gonzalez patent does not preclude patentability as a matter of law because it qualifies as prior art only under the circumstances defined in 35 USC § 103(C). The Gonzalez patent is not available as a reference, and the independent claims 15 and 16 are allowable. Favorable reconsideration of these claims is respectfully requested.

Claim Rejection - 35 USC § 102(b)

Claims 1-11, 13, and 14 stand rejected in paragraph 3 under 35 USC § 102(b) as being anticipated by U.S. Patent No. 6,036,698 to Fawzi et al. (hereinafter Fawzi). Fawzi is directed to a percutaneous tissue biopsy and tissue removal device that includes an expandable tissue cutter and an expandable tubular tissue removal member. Because the diameter of the tissue cutter and tissue removal member are expandable for tissue removal from an initial, small insertion diameter, the percutaneous invasion is less traumatic and a patient experiences faster healing. The Fawzi device is like a snake whose mouth opens wider than the snakes' body to swallow a prey, and whose body then expands to assimilate and pass the swallowed prey.

Figure 1 of Fawzi illustrates a tissue removal member 100 and describes it as having a single lumen both for removal of an excised tissue specimen and for positioning a cutting member 300 (Col. 4, lines 64-67 and Col. 5, line 1). As the Office Action notes, the tissue removal member 100 may be made radially expandable and at least partially radio-opaque (Col. 5, lines 57-66). Figures 2D-E illustrate an embodiment of Fawzi's expandable tissue removal member. The radially expandable tissue removal member is described as allowing the tissue removal member to expand and assimilate "the tissue specimen as it is excised" (Col. 6, lines 54-55). Fawzi further illustrates use of his invention in Figures 14A-F. Figure 14C illustrates the cutting member 300 and the tissue removal member 100 radially expanding in preparation for excising the tissue, *i.e.*, lesion 900. Figure 14D illustrates the tissue 900 being excised by the expanded tissue cutter 300 and advancement of the tissue removal member 100 in the direction of an unnumbered arrow forcing the tissue 900 into the expanded tissue removal member 100. Figures 14D and 14E illustrate the excised tissue within the expanded tissue removal member 100 and gripped by grasping member 500 for removal. Upon completion of the biopsy or tissue removal, the tissue and the tissue removal member 100 are removed from the patient (Col. 5, lines 32-33).

The express purpose of the expandable tissue removal member 100 of Fawzi is to make a small entrance incision, to expand within the body to receive excised tissue, and to provide a transport path, or to contain the excised tissue, for removal from the

patient. Fawzi's device is entirely removed from the patient, contracts around only excised tissue, only temporarily contains the excised tissue to facilitate removal, and functions as a conduit for removal of excised tissue.

The present application is an improvement to the invention that is the subject matter of issued United States Patent No. 6,328,689 B1, LUNG CONSTRICTION APPARATUS AND METHOD; United States Patent No. 6,485,407, TISSUE RESECTION DEVICE, SYSTEM, AND METHOD; and United State Patent No. 6,491,706, CONSTRICTION DEVICE INCLUDING FIXATION STRUCTURES, Serial Number 09/902,821. One aspect of the present invention as defined in independent claims 1 and 14, and as is consistent with the above issued patents, is constriction of an intact (*i.e.,* not severed) body tissue for treatment of leakage, such as air or body fluid, using an elongated sleeve. A device according to the present invention constricts a selected body tissue to prevent leaks. The intact body tissue is drawn into an elongated sleeve whose inside diameter has been expanded. The sleeve is released from its expanded condition and the structure of the sleeve returns the inside of the sleeve towards its native diameter, constricting the body tissue therein in the process. The constriction forms and maintains a seal against leaks without otherwise requiring traditional methods of suturing, gluing, or other closure methods that can often be fraught with complications. Such potential complications include creating additional leaks of air, body fluid such as blood, contaminates, or other adverse results. The constricted tissue obviously will become ischemic and necrotic.

"Sleeve" as used in the application denotes an implantable structure that wholly or partially covers a body tissue for constriction. An elongated sleeve structure of the instant invention is structurally suited for constricting lung tissue and other body organs having more than a single vessel such as a blood vessel or air passageway. For example, lung tissue has many small blood vessels and air passageways that are difficult to seal against leakage. The elongated sleeve structure provides constriction and support over a length of the body tissue.

Applicants submit that the claims of the present invention are not anticipated by Fawzi. To anticipate, Fawzi must be an identical invention in every detail and teach all

the structural limitations of the present claims. MPEP § 2131. "To anticipate under section 102, a prior art reference must disclose all the elements of the claimed invention or their equivalents functioning in essentially the same way." *Shanklin Corp. v. Springfield Photo Mount Co.*, 521 F.2d 609, 187 U.S.P.Q. 129 (1st Cir. 1975). "Not only must all the claimed elements be present in the prior device, but the elements must be found in substantially the same situation where they do substantially the same work." *Gillette v. Warner-Lambert Co.*, 690 F. Supp. 115, 117, 8 U.S.P.Q. 1082, 1084 (D. Mass 1988). "Thus, any degree of physical difference between the patented product and the prior art, *no matter how slight*, defeats the claim of anticipation." *American Permahedge, Inc. v. Barcana, Inc.*, 857 F. Supp. 308, 32 U.S.P.Q. 1801, 1807-08 (S.D.N.Y. 1994).

The Fawzi invention does not anticipate the instant invention for several reasons. A reason Fawzi does not anticipate the instant claims is that the elongated sleeve is structured to remain in the patient constricting the body tissue, while the tissue removal member of Fawzi is structured for removal from the patient at the conclusion of the biopsy procedure. Another reason Fawzi does not anticipate the instant claims is the elongated sleeve is structured to permanently constrict intact body tissue while the tissue removal member of Fawzi is structured to temporarily contract around only wholly or partially excised body tissue pending removal from the body. A further reason Fawzi does not anticipate the instant claims is intact body tissue is directly received in the elongated sleeve while Fawzi cannot receive the body tissue in the tissue removal member until the body tissue has been at least partially excised by cutting member 300. A still further reason Fawzi does not anticipate the instant claims is the elongated sleeve when in the expanded condition, or when released from the expanded condition, does not act as a conduit facilitating removal of excised tissue as does the tissue removal member 100 of Fawzi. A yet further reason Fawzi does not anticipate the instant claims is that the constriction provided by the elongated sleeve structure of the instant claims enables suppression of leaks from otherwise intact body tissue.

The independent claims of the instant application claim a body tissue constriction method and device that is configured to contain and constrict a body tissue, the body

tissue may be at least a portion of an intact part of organ. The constriction suppresses leaks, internal bleeding and escape of body fluids. The Fawzi biopsy device is neither suited for nor described as being suited for this purpose. The Fawzi biopsy device could not be used in the same situation for the same purpose as the instant invention described in the claims. Using the Fawzi to treat a body tissue would create the very problems the instant invention seeks to avoid. For example, constricting a lung portion with the Fawzi device would remove the lung portion and would leave behind a bleeding lung that would collapse and endanger a patient's life because of unsealed air leaks and blood loss.

Based on the above distinctions, it is respectfully submitted that the Fawzi biopsy device is completely different in structure and function from the body tissue constriction device defined in independent claims 1 and 14. Not all of the claimed elements are present in the Fawzi device. The elongated sleeve formed to receive body tissue of the instant invention is not present in the tissue removal device of Fawzi, which is only structured to receive excised body tissue for removal of both the excised body tissue and the tissue removal device from the patient.

Furthermore, the elements are not found in substantially the same situation where they do substantially the same work. As described above, the elongated sleeve constricting tissue within the body is found in a substantially different work situation than the tissue removal device receiving excised body tissue for removal. The elements simply perform different work. The elongated sleeve remaining in the body and constricting body tissue, and the tissue removal device providing a means for removing excised tissue and being removed itself at the conclusion of the procedure.

From the above, it is respectfully submitted that all claims to the device defined in independent claims 1 and 14 are clearly allowable over Fawzi. Fawzi fails to describe an identical invention in every detail. Favorable consideration is respectfully requested.

Claim Rejection - 35 USC § 103 Alferness

Claims 1-14 stand rejected in paragraphs 4 and 5 under 35 USC § 103(a) as being obvious and unpatentable over U.S. Patent No. 6,126,590, CARDIAC

REINFORCEMENT DEVICE, to Alferness. The argument and citations of applicants' prior Amendment and Response filed on about September 18, 2002, related to Alferness are incorporated herein by reference.

The standard for obviousness is:

> To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP 2142.

Alferness is directed to a cardiac reinforcement device (CRD) or support jacket that limits the outward expansion of a heart wall during diastolic chamber filling beyond a predetermined size. The Alferness size-adjustable jacket is applied over a heart to confine and preclude expansion of the heart as a therapy for ventricular dilation. The degree of expansion constraint applied to the heart by a CRD is predetermined by the physician based on, for example, cardiac output performance or cardiac volume. The CRD of Alferness provides cardiac reinforcement that constrains cardiac expansion during diastolic filling of the heart to a predetermined size, but does not impair systolic function. While Alferness' support jacket can be made from inflexible material, it is preferably sufficiently flexible to move with the expansion and contraction of the heart without impairing cardiac function (Col. 3, lines 1-21). The CRD of Alferness limits the outward expansion of a heart by confining it to a maximum volume defined by a predetermined size of a jacket. The CRD does not provide a continuous compressive force that minimizes the volume of a heart. This would impair the function of the heart and kill the patient.

The size adjustable CRD of Alferness includes a jacket structure that opens and closes by virtue of a slot having edges that can be moved apart to open and drawn together to close and adjust the size. The CRD includes a jacket 15 having a slot 19 with opposed lateral edges 20 and 21 that allow it to be opened like a jacket or

cardigan, and then lateral fasteners 22 and 23, such as laces, allow the edges to be drawn together by the surgeon "for selectively adjusting the volumetric size of the jacket 15" (Col. 6, lines 34-43). The selective adjustment establishes the limit on outward expansion of the heart.

The Office Action describes the jacket of Alferness as being released from the expanded condition. Release means to "allow (something) to return to its resting position by ceasing to put pressure on it." *The New Oxford American Dictionary* 1438 (2001). The CRD is not released from an open-receiving configuration to receive a heart to an expansion-limiting configuration to limit expansion of a heart. Rather the opposed lateral edges 20 and 21 of CRD jacket are mechanically drawn toward each other by the surgeon using the lateral fasteners 22 and 23. The edges are drawn together by the surgeon sufficiently to establish the predetermined maximum heart size. Furthermore, the structure of the CRD does not draw the edges toward each other.

The CRD of Alferness may include an inflatable member 54 for selectively adjusting the size of the jacket 53 (CRD) as cardiac volume reduces in response to the size constraint imposed by the jacket 53 over time, which is illustrated in Figure 6 (Col. 7, lines 20-23).

> According to this embodiment, the inflatable member is mounted between the jacket and the epicardium. The volumetric size of the jacket can be reduced by inflating the inflatable member through an inflation port with, for example, a gas or liquid. As cardiac expansion volume responds to cardiac constraint by size reduction, the predetermined size of the jacket can then be reduced by inflating the inflatable member within the jacket. Once inflated, the size of the inflatable member is preferably maintained until therapeutic response causes a need for further inflation. According to the invention, the inflation of the inflatable member provides a reduction in the predetermined size of the jacket by a fixed increase in volume of the inflatable member. The inflatable member is not rhythmically inflated and deflated to provide assistance to cardiac contraction during systole.

(Col. 5, lines 7-22). The inflatable member 54 includes a filling apparatus 57 for entry of a fluid to inflate the inflatable member.

The Office Action considers an expanded condition to occur when the jacket 53 is previously fitted in a predetermined size around the heart 56 and the inflatable

member 54 is present in a deflated configuration (prior to expansion). The Office Action then considers a constricted condition to occur when the inflatable member 54 is inflated to further reduce the predetermined size of the jacket 53. The Office Action is silent about how inflation of the inflatable member 54 with a fluid from the external apparatus 57 might be considered a release of the jacket 53 from the expanded condition.

As the quote above from Col. 5, lines 7-22, of Alferness clarifies, inflation of the inflatable member 54 is only to compensate for the therapeutic reduction in cardiac expansion volume provided by the cardiac reinforcement device by further reducing the maximum cardiac expansion volume (Col. 4, lines 15-16). Inflation of the inflatable member 54 further reduces the predetermined size (and internal volume) of the jacket 53, and its corresponding limitation on the outward expansion of the heart wall during diastolic chamber filling. Inflation of inflatable member 54 is a post-surgical adjustment allowing incremental reduction in diastolic expansion as the cardiac size is reduced by the healing process, but does not provide any form cardiac constriction. The express purpose of the Alferness device is to improve the function of the heart in those areas of the heart where the jacket is applied. While the Alferness jacket may confine the heart during diastolic expansion to reinforce or support the heart, it neither collapses nor constricts the heart.

Previous portions of this paper have described the structure and function of the invention as defined in independent claims 1 and 14. Alferness does not meet any of the three basic criteria for obviousness. He does not show, teach, or suggest all of the structural limitations of these claims. Specifically, Alferness does not suggest or motivate one to modify the cardiac reinforcement device to permanently constrict a body tissue to suppress leaks. Reinforcement of an organ and constriction of a tissue are significantly different concepts. Alferness does not include any description related to treating a heart condition by constriction because constriction of the heart would probably kill the patient. Alferness does not show, teach, or suggest a constriction device that is expandable to receive body tissue and that automatically constricts the body tissue when released from the expanded condition. Alferness describes a heart-

size limitation device for structurally supporting and healing a diseased heart by controlling the predetermined maximum size (or volume) of the heart, and adjusting the predetermined size as the heart heals. Alferness does not provide a reasonable expectation of success in constrictively inhibiting leaks from body tissue with a device described in his patent. Lastly, Alferness does not teach or suggest all the claim limitations of the instant invention.

In view of the foregoing, it is respectfully submitted that independent claims 1 and 14 are allowable over Alferness, and the claims dependent on claim 1 are likewise allowable. Favorable reconsideration is respectfully requested.

CONCLUSION

Original claims 1-14 and previously added claims 15 and 16 remain in the application, and have been presented here for examination. For the foregoing reasons, it is respectfully submitted that independent claims 1 and 14-16 are in condition for allowance. Since the remaining claims are dependent from these claims, these claims are likewise considered to be in condition for allowance.

By the foregoing, this paper responds fully to all of the concerns expressed in the Office Action, and has demonstrated that each of the pending claims is in condition for immediate allowance. Favorable reconsideration and allowance of the pending claims are therefore respectfully requested. If the Examiner believes that a phone interview would be helpful, a phone call to the undersigned at (425) 455-5575 is respectfully encouraged.

Respectfully submitted,

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Attachments: Copy of recorded assignment

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